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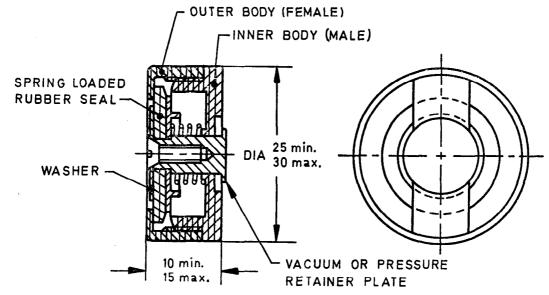


Indian Standard

SPECIFICATION FOR VALVES FOR SUCTION SOCKET FOR ARTIFICIAL LIMBS

(First Revision)

- 1. Scope Dimensional and functional requirements of valves for suction socket used in above knee prosthesis sockets (total contact socket) for artificial limbs.
- 2. Shape and Dimensions As shown in Fig. 1.



All dimensions in millimetres.
FIG. 1 SUCTION SOCKET VALVE

3. Material

- 3.1 Light weight material, such as aluminium alloys or plastics, may be used. The maximum weight of the valve assembly shall not exceed 25 g.
- 3.2 The plastics shall be non-toxic, non-irritant and inert to the body fluids.
- 3.3 The rubber sealing shall be of synthetic quality resistant to body fluid and shall be non-toxic.
- 3.4 The spring steel wire shall conform to the requirements of IS: 4454 (Part 2)-1975 'Steel wires for cold formed springs: Part 2. Oil hardened and tempered spring steel wire and value spring wire—unalloyed (first revision)'.
- 3.5 The materials used shall conform to the requirements specified in the relevant Indian Standards wherever applicable.

4. Workmanship and Finish

- 4.1 The valve shall permit no air leak between outer and inner body. The spring used to control suction shall maintain suitable compression on sealing when assembled.
- 4.2 The spring shall be fully hardened and tempered.
- 4.3 The valve shall have a smooth finish and robust construction.

5. Functional Requirements

5.1 An outer body (female) shall be capable of getting secured permanently into the socket either by lamination or by adhesive fixing. It shall also be able to adopt the male body from outside the socket preferably by screwing or other such quick process.

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- 5.2 The inner body may be directly screwed or pressed into the outer body (female) of the socket.
- 5.3 A spring loaded rubber seal shall be sandwiched between outer and the inner body in such a manner that the air passage from outer to inner body can be completely blocked when outer body is screwed into the inner body. It shall also be easily possible to establish air contact (for release of vacuum or pressure) between inner and outer body by manual push or pull system of the spring loaded seal from outside the socket.
- 5.4 A representative configuration of one such design is indicated in Fig. 1 explaining these main elements of the system. Any other design conforming to the above requirements shall also be acceptable.

6. Tests ∗

- 6.1 Leak Proofness The valve shall be leakproof when assembled on socket. The test procedure shall be as given in 6.1.1 and 6.1.2.
- 6.1.1 The valve shall be suitably connected to a closed space having volume of not less than 1 litre and not more than 1.1 litre. The air in the closed space shall be evacuated by means of a vacuum pump to obtain a vacuum of 80 percent (20 kN/m²). The vacuum pump shall then be stopped and drop in vacuum shall be noted.
- 6.1.2 The drop in vacuum shall not exceed 20 percent in 20 minutes that is the pressure inside shall not exceed 40 kN/m².
 - Note The vacuum shall not normally be achieved in actual use of the prosthesis where these valves are fitted. However, to ensure reliable and trouble free service, the above test shall be performed. All precautions shall be taken to ensure total cleanliness of the valve. Valve seal shall be properly lubricated prior to test.
- 7. Marking Each valve shall be suitably marked with the manufacturer's name, initials or recognized trade-mark.
- 7.1 ISI Certification Marking Details available with the Indian Standards Institution.
- 8. Packing As agreed to between the purchaser and the supplier. The valves shall be protected against damages in transit.
- 9. Sampling Sampling scheme and critertia for acceptance shall be as agreed to between the manufacturer and the purchaser. However a recommended sampling plan is given in Appendix A.

APPENDIX A

(Clause 9)

SCALE OF SAMPLING AND CRITERIA FOR CONFORMITY

- A-1. Lot In any consignment, all the valves produced from the same material of the same shape and dimension shall be grouped together to constitute a lot.
- A-2 The number of valves to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SCALE OF SAMPLING				
Lot Size	Samp!	le Size		
Up to 2	5	3		
26, 5	D	•		
51 ., 10	0 8	1		
101 ,, 150	13	!		
151 and a	bove 20			

- A-2.1 These valves shall be selected at random and in order to ensure the randomness of selection, procedures given in IS: 4905-1968 'Methods for random sampling' may be followed.
- A-3. Number of Tests and Criteria for Conformity All the valves selected at random in accordance with col 1 and 2 of Table 1 shall be tested for shape and dimensions, workmanship and finish, functional requirements and leak-proofness. The lot shall be considered as conforming to these requirements if none of the valves fail to meet in any of these requirements.